

PSJ16 – Rite Aid Opp Br to Defs Dkt # 1779

Exhibit 7



U.S. Department of Justice

Civil Division
Commercial Litigation Branch
Fraud Section

AM:NAWaites
46-16-3373

Natalie A. Waites
Telephone: (202) 616-2964
E-Mail: Natalie.A.Waites@usdoj.gov

<i>175 N Street, N.E.</i>	<i>P.O. Box 261</i>
<i>Room 10.222</i>	<i>Ben Franklin Station</i>
<i>Washington, DC 20002</i>	<i>Washington, D.C. 20044</i>
<i>[Overnight Address]</i>	<i>[Regular Mail Address]</i>

June 20, 2019

Via Electronic Mail

Special Master Cohen
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, OH 44113-1837
David@SpecialMaster.Law

Re: In re National Prescription Opioid Litigation, No. 17-md-2804;
Response to Motion to Compel Filed by Rite Aid of Maryland, d/b/a Mid-Atlantic
Customer Support Center

Dear Special Master Cohen:

This letter is in response to the letter submitted to you on June 14, 2019, on behalf of Rite Aid of Maryland d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"), in which Rite Aid requests an order (1) compelling the testimony of Donald Tush, a Diversion Investigator for the Drug Enforcement Administration ("DEA"), (2) compelling the production of documents requested by Rite Aid, and (3) overruling assertions of the law enforcement and deliberative process privileges.

As discussed more fully below, Rite Aid's request should be denied for three separate and independent reasons: (1) the documents were not properly subpoenaed, (2) Rite Aid cannot demonstrate a compelling need for the documents and testimony that outweighs the burden to the DEA, and (3) the documents sought are privileged.

I. ARGUMENT

A. Rite Aid did not properly subpoena the requested documents.

Rite Aid moves to compel production of documents that it has not properly subpoenaed. First, the subpoena Rite Aid served on Mr. Tush on January 25, 2019, requested only Mr. Tush's testimony and did not include a request for documents. *See* Rite Aid Mot., Exh. A. Rather, the

documents were requested in an accompanying letter addressed to Assistant U.S. Attorney James Bennett. The letter, which also set forth the subjects on which Rite Aid requested Mr. Tush's testimony, was necessary to satisfy the Department of Justice's (DOJ) *Touhy* regulations that govern the disclosure of official DOJ information by federal employees and agencies, including the DEA. 28 C.F.R. § 16.22(a). A subpoena issued to the appropriate agency is still required, however, before a motion to compel can be enforced. Accordingly, Rite Aid should have issued a subpoena to the DEA, either concurrent with the *Touhy* request letter, or, at a minimum, upon receiving the *Touhy* denial. Because there is no subpoena to enforce, Rite Aid's motion to compel is premature.

Second, even if Rite Aid had requested documents in its subpoena, which it did not do, the request would still be improper because the subpoena was addressed to Mr. Tush. A request for DEA documents should be addressed to the DEA, and not to individual agency witnesses. A subpoena may "command each person to whom it is directed to ... produce designated documents ... in that person's possession, custody, or control." Fed. R. Civ. P. 45(a)(1)(A)(iii). Mr. Tush is not the record custodian for the documents requested, and he does not maintain investigation reports in his personal possession. In the absence of a proper subpoena for the requested documents, a motion to compel their production is premature.

B. The requested documents and testimony are disproportionate to the burden of production, and Rite Aid is unable to show a compelling interest.

Discovery is limited to information that is both "relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). In light of the fact that the United States is not a party to this litigation, the court must also consider the *Touhy* regulations, which serve an important public policy function: the government has a "legitimate interest in orderly governmental operations and the proper use of officials' time." *Alex v. Jasper Wyman & Son*, 115 F.R.D. 156, 157 (D. Me. 1986). These concerns are especially significant when there is a request for live testimony from a federal agency. In the face of a request for a deposition, "an agency's choice of whether or not to comply with a third-party subpoena is essentially a policy decision about the best use of the agency's resources." *Puerto Rico v. United States*, 490 F.3d 50, 61 (1st Cir. 2007). Once an agency declines to provide testimony "in the context of private litigation when the government is not a party, a court should not order testimony to be given . . . without the showing of a compelling interest." *Alex*, 115 F.R.D. at 157; *see also COMSAT Corp. v. Nat'l Science Found.*, 190 F.3d 269, 278 (4th Cir. 1999).

Rite Aid fails both tests: it can neither establish that its requests are proportional to the burden nor show that it has a compelling interest sufficient to overcome the *Touhy* denial. First, the request for documents related to "Rite Aid Mid-Atlantic's compliance with 21 U.S.C. § 823 and 21 C.F.R. § 1301.74" lacks specificity. Second, there is no meaningful nexus between the parties' claims and defenses and the requests for "completed audits of the Distribution Center" and Mr. Tush's testimony. Third, any limited relevance is significantly outweighed by the burden on the DEA should it be required to respond to this requests, as well as future similar requests. Consequently, the requested discovery is not proportionate to Rite Aid's need, and Rite Aid cannot demonstrate a compelling interest sufficient to overcome the *Touhy* denial.

1. Rite Aid's request for documents related to "Rite Aid Mid-Atlantic's compliance with 21 U.S.C. § 823 and 21 C.F.R. § 1301.74" is vague.

In demanding documents related to "Rite Aid Mid-Atlantic's compliance with 21 U.S.C. § 823 and 21 C.F.R. § 1301.74," Rite Aid's request is so vague as to be meaningless. In fact, the only specific documents that Rite Aid has identified that may be responsive to this request are the completed audits of the Distribution Center. If Rite Aid cannot identify with any reasonable degree of specificity the documents it is seeking, the DEA - as a non-party - should not be compelled to assist Rite Aid in its fishing expedition. Critically, the DEA also already produced thousands of documents and multiple 30(b)(6) witnesses in response to the parties' requests for information on how the DEA has interpreted and applied 21 U.S.C. § 823 and 21 C.F.R. § 1301.74, and this discovery is available to Rite Aid.¹

2. The requested information is of minimal relevance.

Rite Aid asserts that Mr. Tush's testimony and the DEA's reports of investigation will establish that Rite Aid "maintained adequate controls against diversion," including a suspicious order monitoring system that complies with the requirements set forth in the Controlled Substances Act (CSA). *Rite Aid Mot.* at 3. Yet, as counsel for the government explained when meeting and conferring in advance of this motion, the DEA's investigations focused on the site's physical security and record-keeping and simply do not speak to the design or functionality of Rite Aid's suspicious order monitoring system. (Declaration of John Martin at ¶ 10) In fact, the emails Rite Aid attached as Exhibit C, from which Rite Aid selects a number of misleading and out-of-context quotations, outline the systems that were reviewed as part of the scheduled investigations.

As DOJ conveyed to Rite Aid's counsel, and consistent with Rite Aid's own documents, the 2005 report does not contain even a single mention of a suspicious order monitoring system, and the two reports relating to the 2012 investigation contain only a passing mention by Rite Aid of such systems and only in the context of the closing discussion. The DEA is willing to stipulate to the fact that the 2005 and 2012 scheduled investigations were closed without any deficiencies cited.² But Rite Aid seeks to have the DEA actually *endorse* its suspicious order monitoring system. *Rite Aid Mot.* at 2-3 (claiming that documents and testimony would "provide critical evidence of DEA's evaluations and acceptance of Rite Aid Mid-Atlantic's Suspicious Order Monitoring System"). The DEA did not make such an endorsement in the course of its scheduled investigations and declines to do so now.

¹ The United States notes that Rite Aid has dropped its even broader request for DEA's interpretation, enforcement and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 and guidance and communications provided by DEA to Rite Aid Mid-Atlantic regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74. Accordingly, the United States does not respond to that request in this letter.

² Although DEA also conducted a scheduled investigation of the facility in 2009, Mr. Tush did not participate in that investigation and has no first-hand knowledge of it.

Further, even if the DEA had endorsed Rite Aid's suspicious order monitoring system – which it did not – that fact would only answer the question whether Rite Aid could identify suspicious orders. It would not answer the question whether Rite Aid took the appropriate steps upon identifying suspicious orders, which is the question at the heart of the plaintiffs' claims.

3. Producing the requested information would impose a disproportionate burden on the government.

In evaluating a discovery request, a court considers “whether the burden or expense of the proposed discovery outweighs its likely benefit,” Fed. R. Civ. P. 26(b)(1); “the status of a person as a non-party is a factor that weighs against disclosure,” *Am. Elec. Power Co. v. United States*, 191 F.R.D. 132, 136 (S.D. Ohio 1999). Given the minimal value of the DEA's scheduled investigation reports and of Tush's testimony, the burden of producing this information outweighs any benefit to Rite Aid.

Specifically, compelling production here could lay the groundwork for myriad requests for similar documents from other parties during the Track Two and subsequent discovery phases, multiplying the already disproportionate burden placed on the DEA, and further siphoning resources from the DEA's critical mission, which is to detect and prevent diversion. Given the number of scheduled investigations conducted each year and the lengthy time period at issue in the MDL, the DEA could be forced to collect and process thousands of documents, over and above the thousands of documents already produced in response to other requests. Some of these documents exist only in paper form, further complicating the process of collection and production. All reports would require a review to identify and redact privileged information, and to determine whether even a limited disclosure would compromise ongoing investigations. Consequently, the agency's burden must be considered from the perspective of the cumulative burden that will attach if other parties are similarly able to request documents and testimony for the thousands of scheduled investigations that the DEA has conducted during the time period at issue.

Additionally, Rite Aid cannot demonstrate a compelling need because Rite Aid can obtain this information from other sources: its own internal documents and witnesses. In *Alex*, 115 F.R.D. at 157, the defendant sought testimony concerning discussions held between defendant's counsel and an agency witness. In denying defendant's motion to compel the testimony after the agency had denied it under the agency's *Touhy* regulations, the court found that “the defendant's representatives would be competent to testify regarding these discussions” and, therefore, the testimony of the agency witness would be cumulative. The court concluded that the defendant had not demonstrated a compelling need because, while it “presumably . . . would aid defendant's case, it does not appear from the record that it would be essential.” *Id.* The facts here are on all fours – Rite Aid purports to have documents that were drafted contemporaneous with the scheduled investigations, which it attached to its motion, and presumably has access to employees or former employees who met with DEA diversion investigators. It is not entitled to take discovery based on the mere fact that it wishes to use the DEA as a mouthpiece for its defenses.

C. The reports of investigation are privileged.

In response to Rite Aid's request, the DOJ informed Rite Aid that the documents and testimony sought were protected by the deliberative process and law enforcement privileges. While the DOJ continues to posit that reports of investigation for scheduled investigations may, at times, be subject to the deliberative process privilege, the DEA withdraws that privilege with respect to the closed scheduled investigation reports that Rite Aid seeks to request. The DEA maintains, however, that the reports are protected from disclosure by the law enforcement privilege. Contemporaneous with this response, the DEA is providing the declaration of John Martin, Assistant Administrator for the Diversion Control Division, to formally assert the law enforcement privilege on behalf of the DEA.

1. The law enforcement privilege protects the reports even though they contain factual information.

Courts have long recognized that reports containing factual data may nonetheless be protected if "the disclosure of which would reveal law enforcement techniques and investigative evaluations." *Tuite v. Henry*, 181 F.R.D. 175, 180 (D.D.C. 1998), *aff'd*, 203 F.3d 53 (D.C. Cir. 1999) (denying plaintiff's motion to compel an internal report that contained summaries of the investigation and witness interviews).³ Similarly, the DEA's reports include factual data, but these facts exist within scheduled investigation reports that could reveal investigative methods. The investigators' reports reveal not only how they evaluated the facts, but also key investigative decisions, such as:

- The times and durations of DEA scheduled investigations
- The number of substances audited by the DEA
- The type(s) of substances investigated by the DEA
- The manner in which the DEA selects substances to investigate
- The type(s) of records examined by the DEA
- The components of physical security most important to DEA investigators
- The type(s) of intelligence collected by the DEA from facility operators

³ *Tuite* provided a list of ten non-exhaustive factors to consider when determining whether to pierce the law enforcement privilege: "(1) the extent to which disclosure will thwart governmental processes by discouraging citizens from giving the government information; (2) the impact upon persons who have given information of having their identities disclosed; (3) the degree to which governmental self-evaluation and consequent program improvement will be chilled by disclosure; (4) whether the information sought is factual data or evaluative summary; (5) whether the party seeking discovery is an actual or potential defendant in any criminal proceeding either pending or reasonably likely to follow from the incident in question; (6) whether the investigation has been completed; (7) whether any interdepartmental disciplinary proceedings have arisen or may arise from the investigation; (8) whether the plaintiff's suit is nonfrivolous and brought in good faith; (9) whether the information sought is available through other discovery or from other sources; and (10) the importance of the information sought to the plaintiff's case." *Id.* at 177.

See Martin Declaration, ¶ 11.

Furthermore, differences between the reports could reveal changes in the DEA's priorities and methods over time. Given the risk that distributors armed with this information could undermine the DEA's enforcement efforts, the public interest favors nondisclosure. See Martin Declaration, ¶ 14. Significantly, the case relied upon by Rite Aid, *In re Packaged Ice Antitrust*, No. 08-md-01952, 2011 WL 17990189 (E.D. Mich. May 10, 2011), which cites approvingly to the factors listed in *Tuite*, does not stand for the proposition that evaluative reports, such as the ones at issue here, are not privileged. In *Packaged Ice*, the government sought to withhold recordings and verbatim transcripts which had previously been shared with one party to the litigation. *Id.* In the present case, the investigative reports are not mere transcripts; rather, they reflect the thought processes of the investigators conducting the scheduled investigation, and have not been shared with any party.

Nor does the passage of time preclude application of the law enforcement privilege. See, e.g., *Tuite*, 181 F.R.D. at 181 ("While the public interest in nondisclosure may lessen somewhat at the conclusion of a criminal investigation, it does not dissipate entirely.") These scheduled investigations have concluded, but they are merely two reports in a standardized program that continues today. As such, it remains as critical now to protect the investigative methods detailed in the reports as it was in 2005 and 2012. Cf. *United States v. Gaver*, No. 3:16-CR-88, 2017 WL 1134814, at *4 (S.D. Ohio Mar. 27, 2017) (denying discovery of government's investigative tools because doing so "would severely compromise future investigations, and could allow others to develop countermeasures"). The need is particularly acute here: all parties can agree that the opioid epidemic remains one of the most pressing issues facing the United States. Disclosures that will only make it easier for unscrupulous parties to circumvent the CSA's requirements and harder for the DEA to detect such violations are counter-productive to the goal of this MDL and broader public policy imperatives.

2. Rite Aid's need cannot overcome the law enforcement privilege.

Finally, the privilege applies because Rite Aid cannot demonstrate a countervailing need for the documents. A party seeking discovery can overcome the law enforcement privilege only if its interest in discovery outweighs the public's interest in nondisclosure, *Gaver*, No. 3:16-CR-88, 2017 WL 1134814, at *3, but that is not the case here. Specifically, "[t]he privilege is only overcome when the information 'is relevant and helpful to the defense of an accused, or is essential to a fair determination of a cause.'" *United States v. Harney*, No. CR 16-38-DLB-CJS, 2018 WL 1145957, at *10 (E.D. Ky. Mar. 1, 2018) (quoting *United States v. Sierra-Villegas*, 774 F.3d 1093, 1098 (6th Cir. 2014)); see also *Tuite*, 181 F.R.D. at 183 (explaining that the "importance of the information sought to [the party's] case" has been described as the test's "most crucial and important factor."). As discussed above, the reports simply do not establish that Rite Aid's suspicious order monitoring system operated to prevent diversion, so they are neither relevant nor helpful. Nor are they essential: Rite Aid could obtain this same information from its own documents and witnesses. Thus Rite Aid's minimal need for the reports cannot overcome the law enforcement privilege.

II. CONCLUSION

For the foregoing reasons, the government respectfully requests that the Special Master deny Rite Aid's motion to compel. To the extent that it would be helpful, the DEA is willing to make the 2005 and 2012 reports of investigation available to the Special Master for an *in camera* inspection.

Furthermore, should the Special Master consider granting Rite Aid's motion, the DEA respectfully requests that:

- (1) The production be limited to the three reports of investigation in which Mr. Tush was involved (2005 and 2012);
- (2) Any deposition of Mr. Tush be limited to no more than three hours; and
- (3) Any order expressly state that it is limited to the narrow set of facts presented by Rite Aid, and it should not be construed as a blanket permission for other parties to seek the collection of similar documents and testimony related to DEA reports of investigation in general. This qualification would limit the burden placed upon the government by the numerous parties in this multidistrict litigation.

Very truly yours,

/s/ Natalie A. Waites

Natalie A. Waites
Senior Counsel
Commercial Litigation Branch
Civil Division

cc: (with enclosures)

Plaintiffs' Counsel (mdl2804discovery@motleyrice.com);
Defendants' Counsel (xALLDEFENDANTS-MDL2804-Service@arnoldporter.com)
Kelly A. Moore (Kelly.moore@morganlewis.com)

4. The Assistant Administrator for Diversion serves as the principal advisor to the DEA's Administrator and is responsible for all matters related to DEA's diversion efforts both domestically and internationally.

5. I submit this declaration in support of the formal assertion of the law enforcement privilege and ongoing investigation privilege (collectively, "law enforcement privilege") as to the documents and information described below in ¶ 6, documents which concern matters, issues, and investigations which were under the control and supervision of Diversion. I base this declaration on my personal knowledge, information made available to me in the performance of my official duties, including the advice of counsel, and my knowledge of the issues being litigated in this case.

6. I am aware that Rite Aid of Maryland d/b/a Mid-Atlantic Customer Support Center ("Rite Aid") requested that DEA produce documents and information described as "audits of Rite Aid's Distribution Center in Perryman, Maryland," among other information. I have personally reviewed: (1) Report of Investigation (DEA 6) for scheduled investigation for Rite Aid Mid-Atlantic, 601 Chelsea Road, Aberdeen, Maryland 21001 dated September 22, 2005 (hereinafter referred to as "2005 Report"); and (2) Reports of Investigation for scheduled investigation of Rite Aid Mid-Atlantic, 601 Chelsea Road, Aberdeen, Maryland 21001 dated July 6, 2012 and July 30, 2012 (hereinafter referred to collectively, as "2012 Reports"). I understand that these withheld documents will be offered to Special Master David Cohen for an in camera inspection.

7. I believe that to ensure effective policy and decision making by DEA, the law enforcement privileges should be asserted with respect to both the 2005 Report and the 2012 Reports.

8. DEA's primary responsibilities include enforcement of the provisions of the Controlled Substances Act ("Act") as they relate to manufacture, distribution, and dispensing of controlled substances. Pursuant to the Act, DEA administers a comprehensive regulatory scheme intended to prevent, detect and investigate the diversion of controlled substances into illicit channels, and which imposes registration, reporting, and record-keeping requirements upon all persons who manufacture, distribute, or dispense controlled substances.

9. Diversion's mission is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources to illicit ones while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

10. As part of its mission, Diversion conducts scheduled investigations of distribution facilities. The scheduled investigations primarily focus on subjects such as the physical security measures in place and whether the facility maintained accurate records of controlled substances that were received into and distributed from the facilities. The scheduled investigations are not designed to endorse suspicious order monitoring systems. The 2005 Report and the 2012 Reports are Reports of Investigation (DEA 6s) for a scheduled investigation of the Rite Aid facility in Perryman, Maryland.

11. The 2005 Report and the 2012 Reports disclose nonpublic law enforcement sensitive information and techniques, including times and durations of DEA scheduled investigations, the number of substances audited by the DEA, the type(s) of substances investigated by the DEA, the manner in which the DEA selects substances to investigate, the type(s) of records examined by the DEA, the components of physical security most important to DEA investigators, and the type(s) of intelligence collected by the DEA from facility operators.

12. Based on my personal review of the 2005 Report and the 2012 Reports, I believe that disclosure of the entirety or portions of these documents would jeopardize important law enforcement interests by exposing non-public information within the custody or control of a governmental department or agency. In order to carry out DEA's mission of enforcing the Act, DEA Diversion Investigators routinely gather intelligence information and conduct inquiries into potential violations of the Act and potential targets of investigation. Such information is memorialized in Reports of Investigation (DEA 6s), like the 2005 Report and the 2012 Reports, and maintained in investigative files, both for immediate initiation of investigative activity and for future consideration, should additional intelligence become available.

13. DEA does not publicly reveal the substance of its investigations nor publicly disclose whether an individual or organization is an active or prospective target of investigation. DEA maintains the confidentiality of Reports of Investigation, including the 2005 Report and the 2012 Reports. Indeed, the 2005 Report and the 2012 Reports circulated only within DEA and the Department of Justice. Disclosure of the nature, source, and seriousness of intelligence possessed by DEA concerning an individual or organization and of the actions taken by DEA in response to that intelligence would give violators valuable insight into how a future investigation would be conducted. Substantial law enforcement interests would be threatened by disclosing such information, causing significant harm to drug enforcement efforts.

14. Disclosing reports of investigation for scheduled investigations, like the 2005 Report and the 2012 Reports, would severely compromise future investigations by allowing registrants to discern DEA's priorities and methods over time and effectively develop countermeasures to DEA's law enforcement efforts.

15. Disclosure could also expose the names of potential suspects and witnesses, as well as information received from an informant. I believe that revealing such privileged information contained in the 2005 Report and the 2012 Reports described above could jeopardize important governmental and privacy interests; and therefore, the law enforcement privilege should be asserted against these documents.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

6/20/19
Date



John J. Martin
Assistant Administrator for the
Diversion Control Division
Drug Enforcement Administration